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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/648,490	08/25/2000	Robert R. Whittle	5573-124	5616
7590	04/29/2005		EXAMINER	
Myers Bigel Sibley & Sajovec, P.A. Post Office Box 37428 Raleigh, NC 27627				KWON, BRIAN YONG S
		ART UNIT		PAPER NUMBER
		1614		

DATE MAILED: 04/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>
	09/648,490	WHITTLE ET AL.
	<b>Examiner</b>	<b>Art Unit</b>
	Brian S. Kwon	1614

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 28 March 2005.

2a) This action is FINAL.      2b) This action is non-final.

3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 3,4,6 and 8 is/are pending in the application.

4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

5) Claim(s) \_\_\_\_\_ is/are allowed.

6) Claim(s) 3,4,6 and 8 is/are rejected.

7) Claim(s) \_\_\_\_\_ is/are objected to.

8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.

10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) All    b) Some \* c) None of:

1. Certified copies of the priority documents have been received.

2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.

3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date: _____
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
Paper No(s)/Mail Date: _____	6) <input type="checkbox"/> Other: _____



## **DETAILED ACTION**

### ***Summary of Action***

- I. The objection of the disclosure under 35 USC 132 because of the introduction of New Matter in the amendment filed August 03, 2004 is not maintained in light of cancellation of the claim 7.
- II. The rejection of the claims 4-5 under 35 USC 112, second paragraph, is not maintained in light of the amendment.
- III. The rejection of the claims 3-4 and 6 under 35 USC 102(a) as being anticipated by Junggren et al. (US 4255431) is maintained for the reason of record.
- IV. The rejection of the claims 3-7 over claims 18-29 and 32-34 of US'087, 1-5 of US'385, 9-16 of US'086, 1-30 of US'329 and 1-4 of US'324 is not maintained in light of the Applicant's filing of Terminal Disclaimer.

### ***Status of Application***

1. Acknowledgement is made of applicants' filing of the instant application as a Request for Continued Examination (RCE) under 37 CFR 1.1114. Claims 24, 25 and 28 are currently pending for prosecution on the merits.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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2. Claims 3-4, 6 and 8 are rejected under 35 U.S.C. 102(a) as being anticipated by Junggren et al. (US 4255431).

Junggren teaches a composition comprising 2-[2-(3,5-dimethyl-4-methoxy)-pyridylmethylsulfinyl]-(5-methoxy)-benzimidazole (omeprazole), wherein said omeprazole is formulated in various dosage forms (claim 20; column 5, line 59 thru column 7, line 18).

Although Junggren is silent about “a fixed ratio from 5% or less of the 5-methoxy isomer and from 95% or more of the 5-methoxy isomer” or “fixed with a ratio of from 10 percent or less 5-methoxy and from 90 % or more 6-methoxy”, such ratio must be inherently present in the composition, i.e., it was always there. Since 5-methoxy and 6-methoxy isomers is presented in 7:93  $\pm$  2% in omeprazole or commercially available Prilosec (page 5, lines 6-7 and page 18, lines 10-14 of the specification), the referenced composition containing omeprazole “metes and bounds” the claimed invention. Therefore, the reference anticipates the claimed invention.

It is noted to applicant that the fact that applicant may have discovered a new property of omeprazole where omeprazole further comprises 6-methoxy in addition to known 5-methoxy fails to confer patentability to an old composition since such property or characteristic must be inherently present in the old composition. Therefore, the reference anticipates the claimed invention.

*Response to Arguments*

3. Applicant's arguments filed August 03, 2004 have been fully considered but they are not persuasive.

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Applicant's argument in the response takes the position that Junggren's disclosed ratio of 93:7  $\pm$ 2% of the 6- vs. 5-methoxy isomers is derived from the active pharmaceutical ingredient in omeprazole, and not a pharmaceutical formulation as recited in claims 3-4 and 6.

The Examiner disagrees. Unlike applicant's allegation, the interpretation of the instantly claimed ratio of 5-methoxy and 6-methoxy isomers includes the ratios of 5-methoxy and 6-methoxy isomers of the active ingredient of omeprazole. There is no indication in the claims that the claimed ratio must be the ratio in the pharmaceutical composition. Thus, the Examiner maintains that Junggren anticipates the claimed invention.

***Conclusion***

4. No Claim is allowed.
5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Kwon whose telephone number is (571) 272-0581. The examiner can normally be reached Tuesday through Friday from 9:00 am to 7:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached on (571) 272-0951. The fax number for this Group is (703) 872-9306.

Any inquiry of a general nature of relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Brian Kwon  
Patent Examiner  
AU 1614

